Stem Cell Research & Development

Chaophya Hospital
BKK THAILAND
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Name : Prof. Suphachai Chaithiraphan, M.D., FACC., FESC., FRCP., FACP., FRACP., FRCPT., FAMM., FAMS., FASCC.

Qualification: Dip. Thai Board of Internal Medicine and Cardiology,
Dip. American Board of Internal Medicine and Cardiology

Stem Cell Pioneers in Thailand

Objectives of Regenerative Medicine

Utilizing adult stem-cell based therapy to treat degenerative diseases through a less invasive methodology

- Reversal of the disease process
- Inducing recovery
- Improving patients' functionality and well-being
- No current treatments effectively reverse degenerative diseases
- Decreasing health care costs

Degenerative diseases are the major cause of morbidity and mortality

Diabetes

- An incurable chronic disease
- Affects 34.2 million people worldwide

Congestive Heart Failure

- 64.3 million new cases a year
- Largest single expenditure for Medicare
- No therapeutic options other than heart transplant
- 95% of patients die waiting for transplant

Our Mission

We are dedicated to

- Making treatment available TODAY to those in need
- Developing of state-of-the-art cellular technology
- Identifying medical talent in the field of stem cell research and
  treatment
- Connecting exceptional doctors and treatment protocols to patients worldwide
- Providing superior treatment for multiple indications through FDA medical trials

The Technology

- Patients' own blood is used as raw material to manufacture Directed Cell Population
- Cells are cultured under conditions designed to mimic and augment specific natural processes
- A single administration of these cells back into the patient achieves the therapeutic effect

Technology Advantages

- A revolutionary patient-friendly therapy
- No preparatory drug therapy is used
- Blood is obtained using the routine method of blood collection (from the arm vein)
- No surgery or anesthesia is required as the product contains only cells from the patient
- No risk of rejection of cells
- No harmful effects by the implanted cells
- If treated with bone marrow stem cells, they are extracted from the patient's bone utilizing new state-of-the-art painless technology

Processing Logistics

- Cells are presently being processed in Bangkok Thailand under the supervision of Acquest, Swiss Laboratories scientists in partnership with Siriraj Hospital

Company Overview

- Acquest operates and is registered in both Bangkok and Switzerland
- Considered one of the foremost providers of Adult Stem Cell Therapy
  in the world and involved in the industry since 2006
- Together with its affiliates, Acquest has treated more than 400 commercial cases with an extremely high rate of success and safety
- Treatment facility based in Bangkok Thailand, (a premier medical tourism destination)
- Developing cutting edge procedure protocols
- Designing stem cell specific devices
- FDA applications and clinical trials completed
- Establishing new disease protocols
- Aggressive positioning in the academic medical community

Competitive Advantage

- A handful of other companies are targeting similar markets, with differing stem cell technology, however none have the infrastructure
in place to bring the treatments to mass market
- Acquest offers the newest technology available worldwide, has the highest safety standards and follows the most rigorous treatment protocols
- We take a novel approach to the stem cell market by targeting the delivery of therapy rather than exclusively focusing on the
development of cellular products

Marketing

Acquest's primary markets are currently North America, Asia and Europe.

- We connect with patients in the following ways
- A strong focus on news media and patient communication vehicles, using clinical data, testimonials and case studies to illustrate results
- Via internet search results, which are driven by a strategic public relations campaign and web site optimization
- Industry referral program
- Patient referral because of our phenomenal success
- Worldwide patient and physician education seminars

Stem Cell Technology in the USA

- The USA lags behind the rest of the world in both research and treatment utilizing Stem Cell Therapy because of early controversy regarding Embryonic Stem Cells (Regenocyte does NOT use embryonic stem cells)
- FDA approval can be attained in 5 to 7 years by meeting guidelines
  for clinical trials
- Regenocyte Therapeutic will pursue clinical trials with major educational institutions once processing technology has been transferred to Florida Biologix®
- The lack of available commercial Stem Cell therapy treatment in the U.S. has created a HUGE window of opportunity

The Business

By applying professional, cutting-edge approaches to all company activity, Acquest makes innovative, therapeutic, cellular products available in order to reverse the processes of degenerative diseases and aging

The business strategy, initially approaching peripheral markets, guarantees a rapid revenue stream concurrently with establishing a foothold in the major markets
We are establishing partner staging centers throughout Europe and Asia and international markets that will have patient referrals from members of the clinical affiliate program
Example:
1.5 million stent procedures a year facility fee $16,000 X 1,500,000 = $24,000,000,000

Stem Cell Sources

Embryonic

Not used for treatment
Immunosuppressive medication for rejection
Teratoma/cancer risk very high
Loss of regenerative properties due to maturation of cells
Controversial

IPS (Induced Pluripotent Stem Cells)

Very similar to Embryonic cells

Non Embryonic

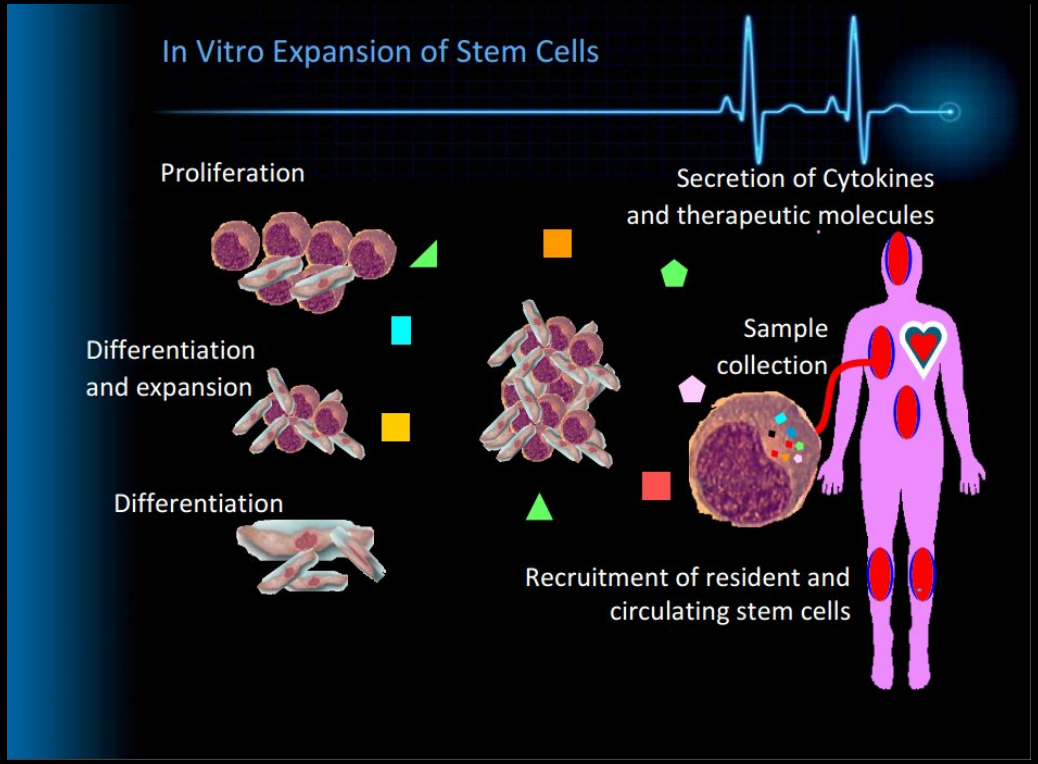
Fetal Stem Cells
Cord/placenta at Birth
Adult Stem Cells
Blood
Bone marrow
Fat and other organs

Advantages and Protocol

Safe and Effective

Acquest only uses Adult Stem Cells directly from the patient to achieve the safest and most effective treatment outcomes similar to Embryonic cells

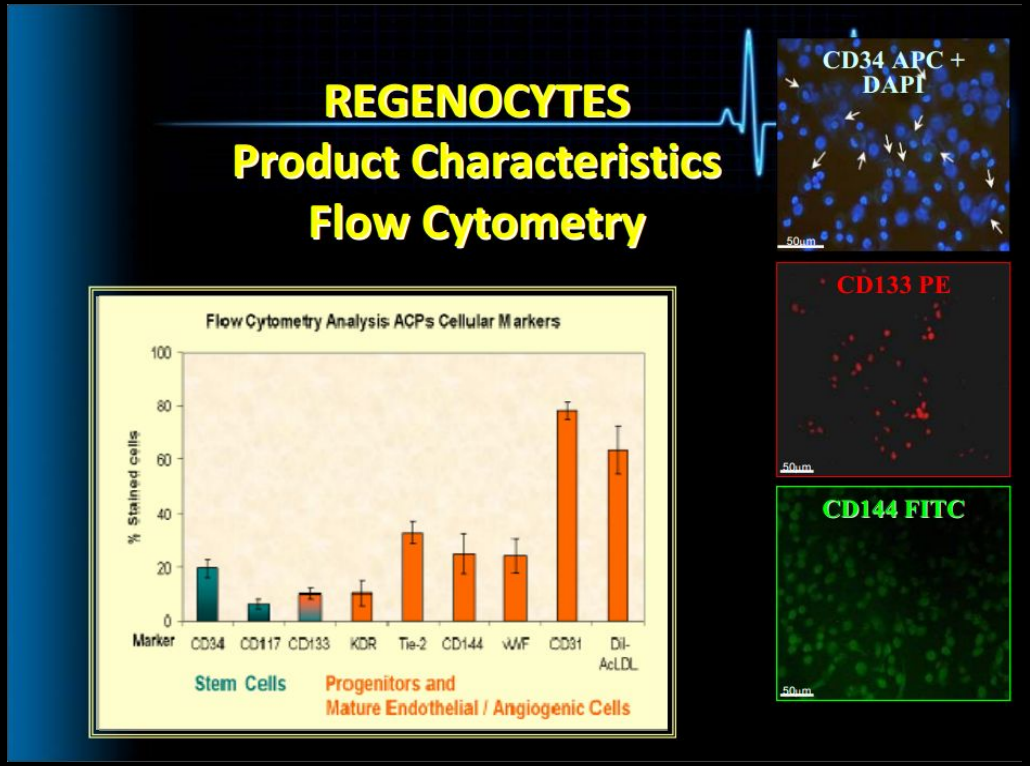
In Vitro Expansion of Stem Cells



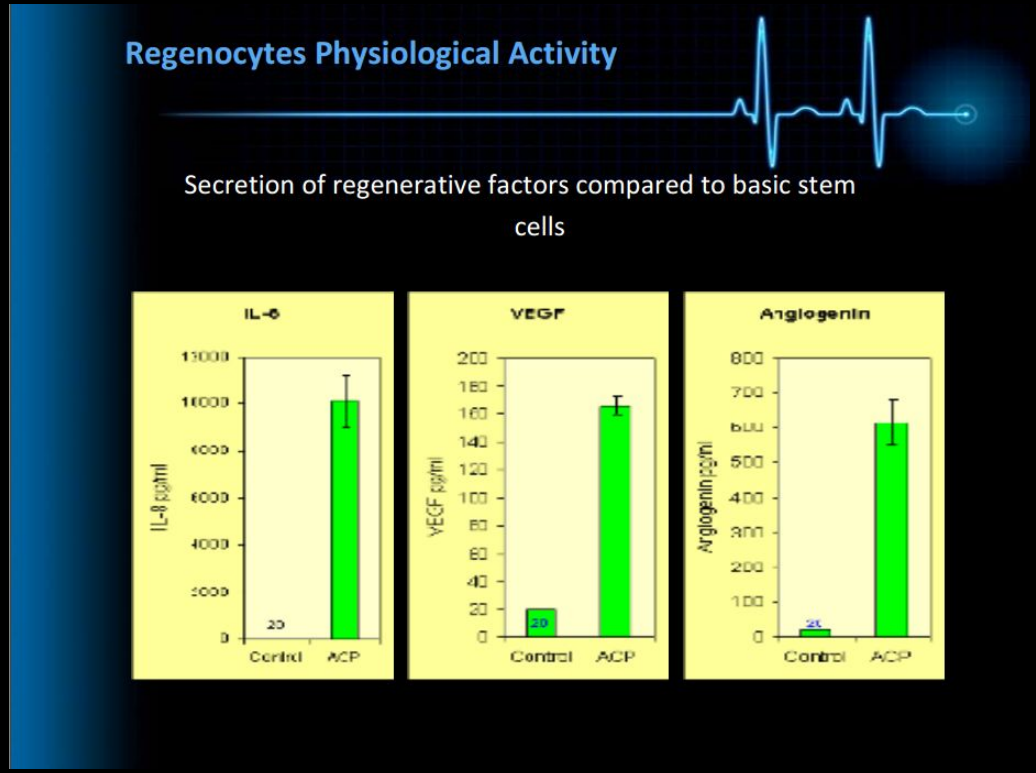
Types of Stem Cells

- Regenocytes are stem cells that have been specifically directed
  and activated for tissue repair or regeneration
- Having additional physiological characteristics from basic
  Hematopoetic and Mesenchymal stem cells

Regenocytes



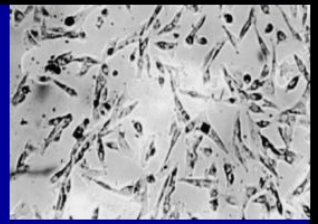
Regenocytes Physiological Activity



Release Criteria

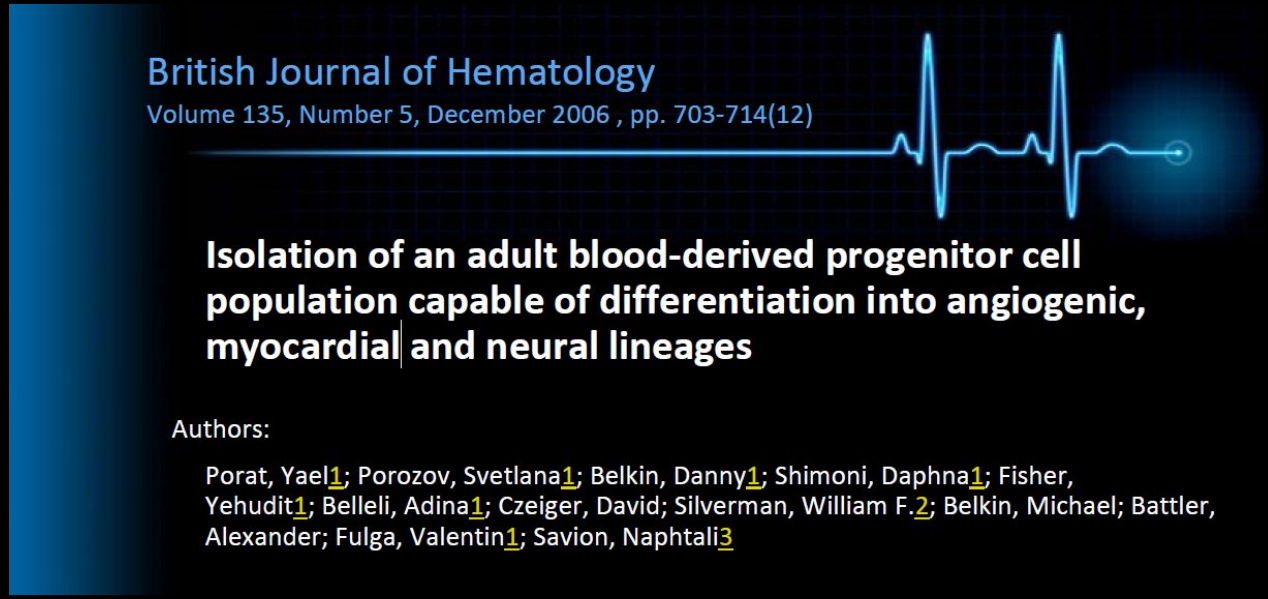
Release Criteria

- >1.5x10^6 ACPs
- Sterile (according to CFR 610.12)
- Endotoxin – negative
- Mycoplasma Ab – negative
- Viability >75%
- Morphology – *spindle-shaped , no color*
- Surface Marker- CD 34 , CD 133 ,KDR,Tie-2,CD144 & CD 31



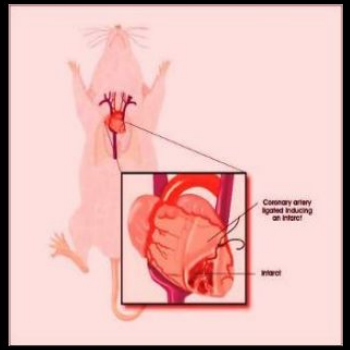
Code of Federal Regulation, US FDA

References


British Journal of Hematology
Volume 135, Number 5, December 2006 , pp. 703-714(12)
Isolation of an adult blood-derived progenitor cell population capable of differentiation into angiogenic, myocardial and neural lineages
Authors:
Porat, Yael1; Porozov, Svetlana1; Belkin, Danny1; Shimoni, Daphna1; Fisher, Yehudit1; Belleli, Adina1; Czeiger, David; Silverman, William F.2; Belkin, Michael; Battler, Alexander; Fulga, Valentin1; Savion, Naphtali3

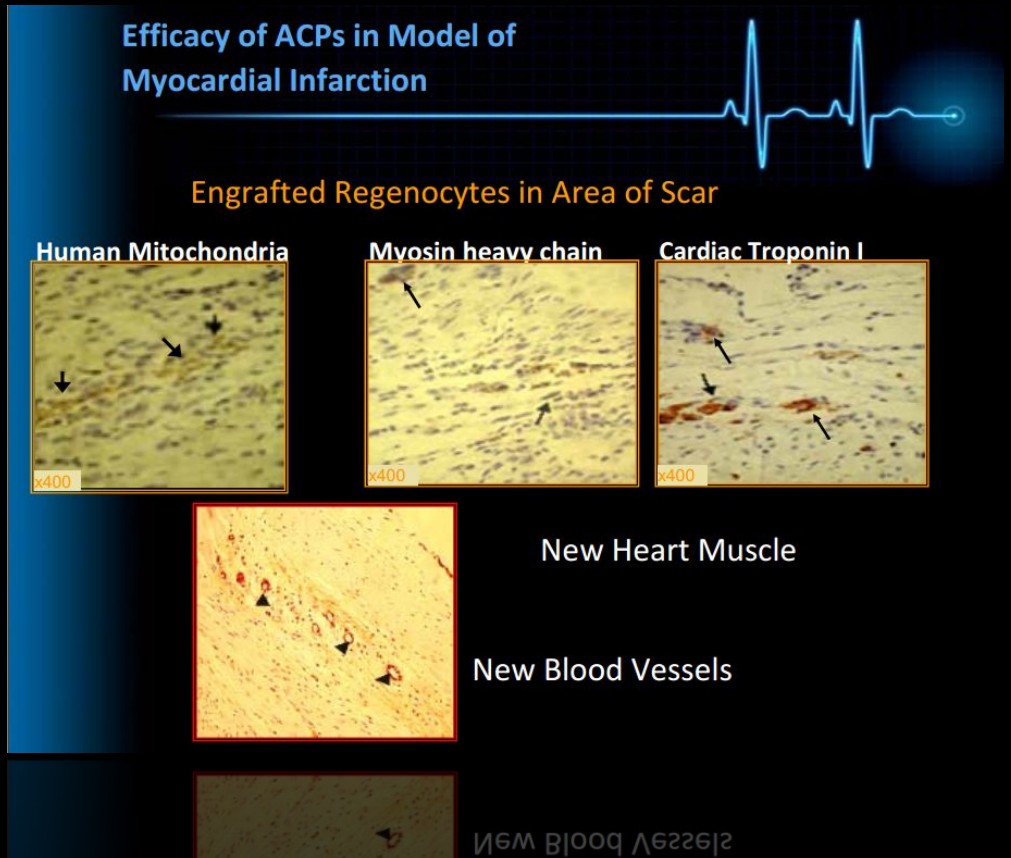
Clinical tests

Efficacy of ACPs in Rat Model of Myocardial Infarction

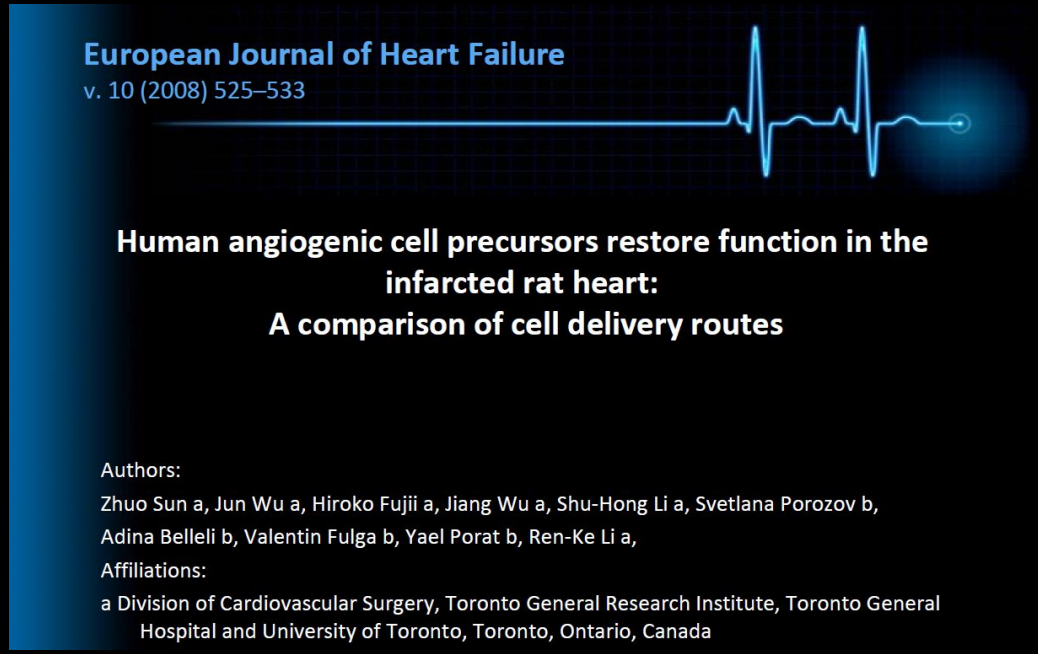


- Myocardial infarction via LAD Ligation in nude rats
- Route of Administration of Regenocytes
  - Intracoronary
  - Intramyocardial

ACPs in Myocardial Infarction



References

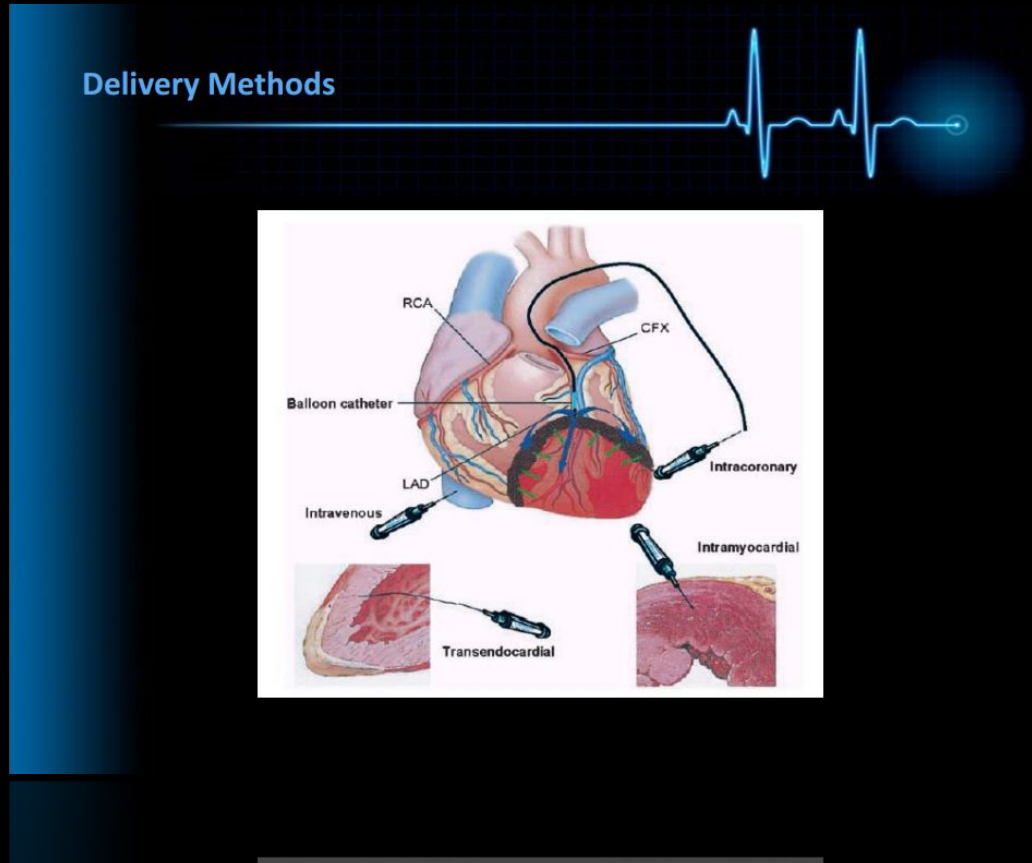


European Journal of Heart Failure
v. 10 (2008) 525–533

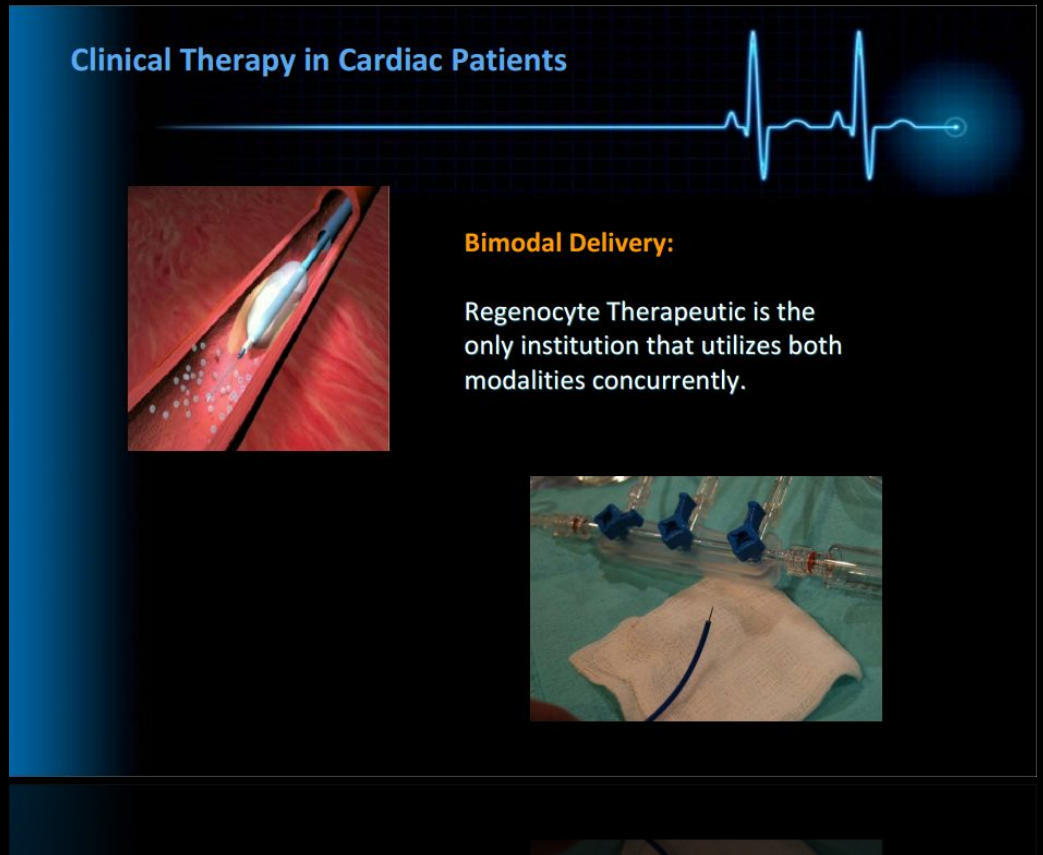
**Human angiogenic cell precursors restore function in the infarcted rat heart:
A comparison of cell delivery routes**

Authors:
Zhuo Sun a, Jun Wu a, Hiroko Fujii a, Jiang Wu a, Shu-Hong Li a, Svetlana Porozov b,
Adina Belleli b, Valentin Fulga b, Yael Porat b, Ren-Ke Li a,
Affiliations:
a Division of Cardiovascular Surgery, Toronto General Research Institute, Toronto General Hospital and University of Toronto, Toronto, Ontario, Canada

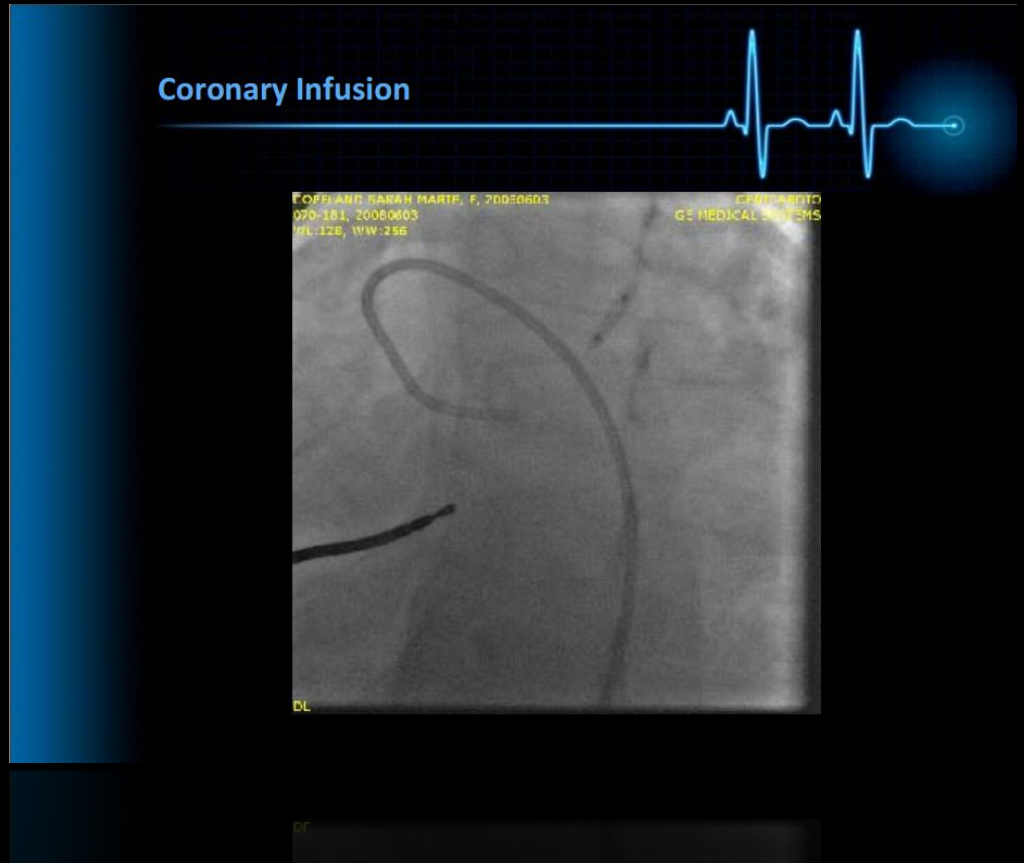
Delivery Methods



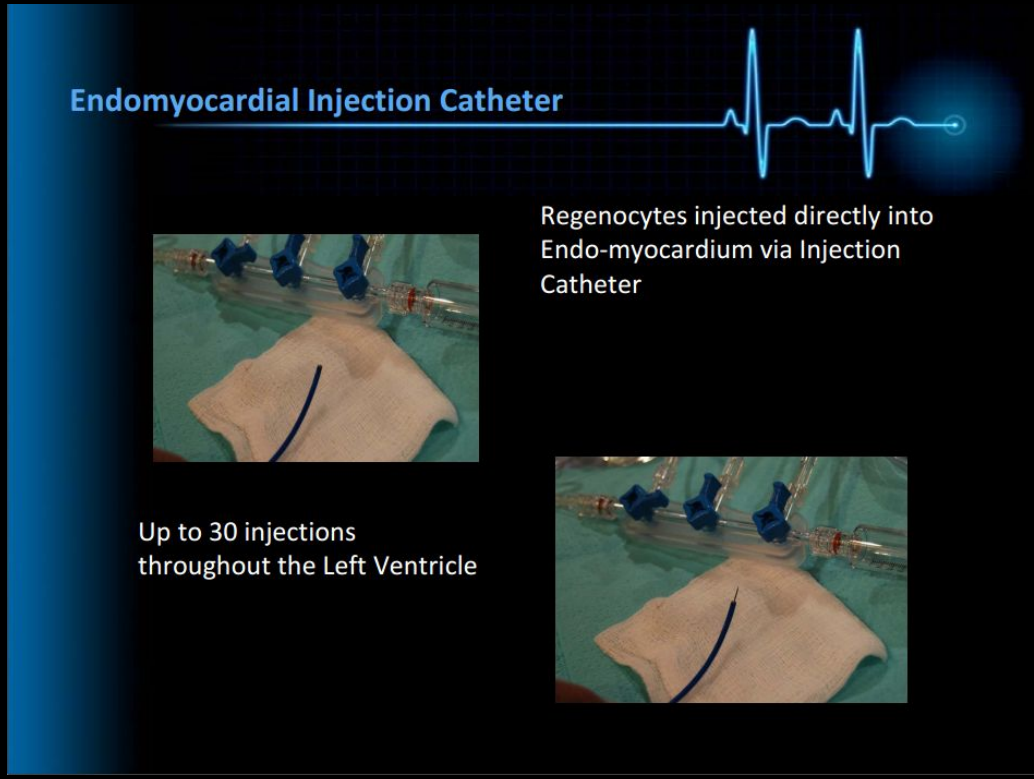
Clinical Therapy in Cardiac Patients



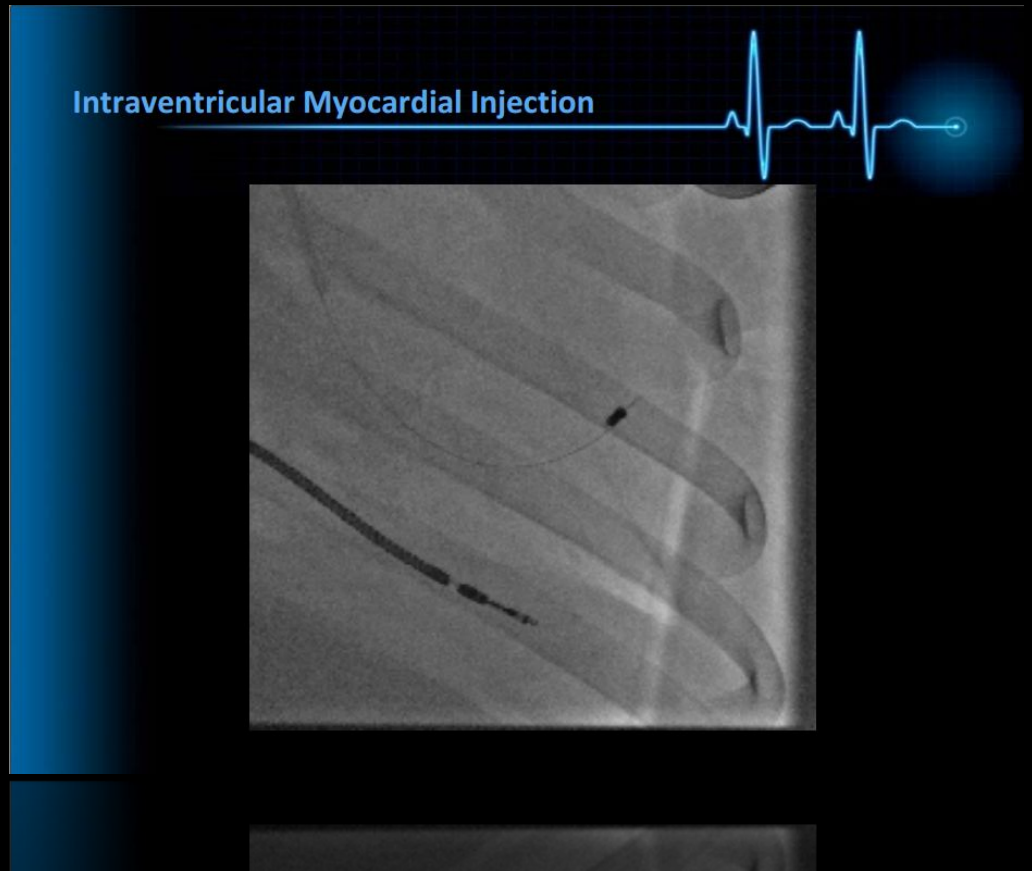
Coronary Infusion



Endomyocardial Injection Catheter



Intraventricular Myocardial Injection

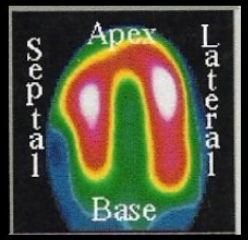


Infarcted Myocardium

Infarcted Myocardium

Anterior Wall myocardial infarct
Resting Nuclear scan

Before Therapy Ejection Fraction 30%

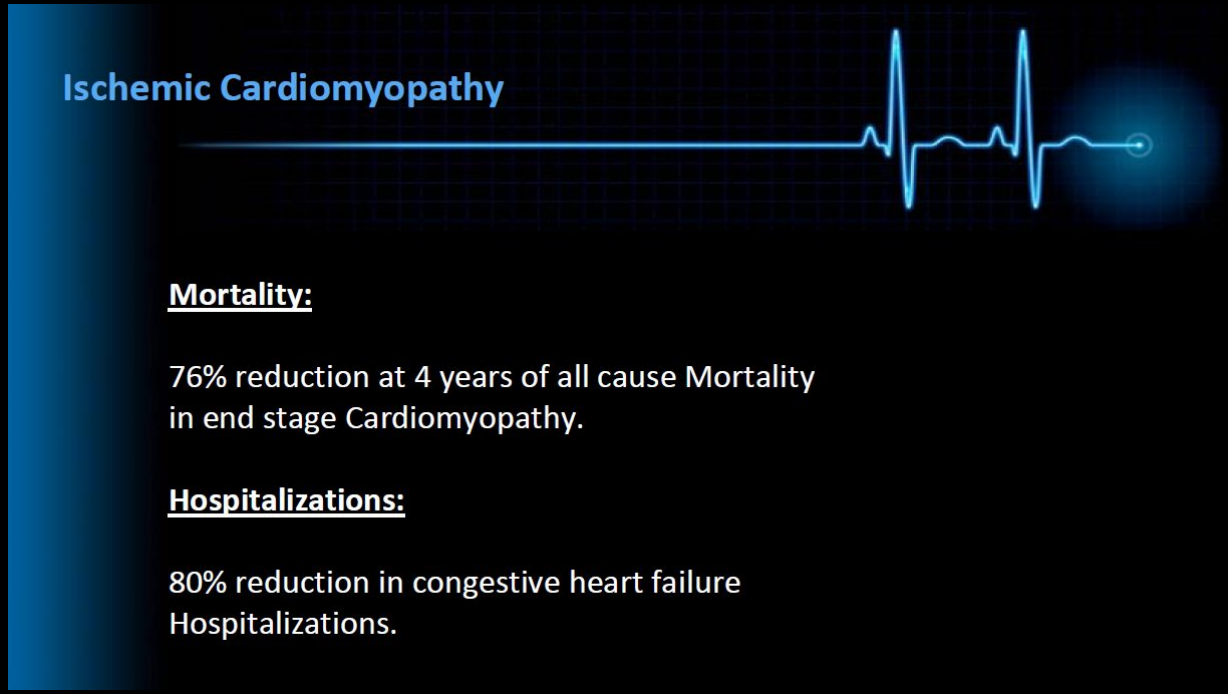


Anterior Wall myocardial infarct
Resting Nuclear scan

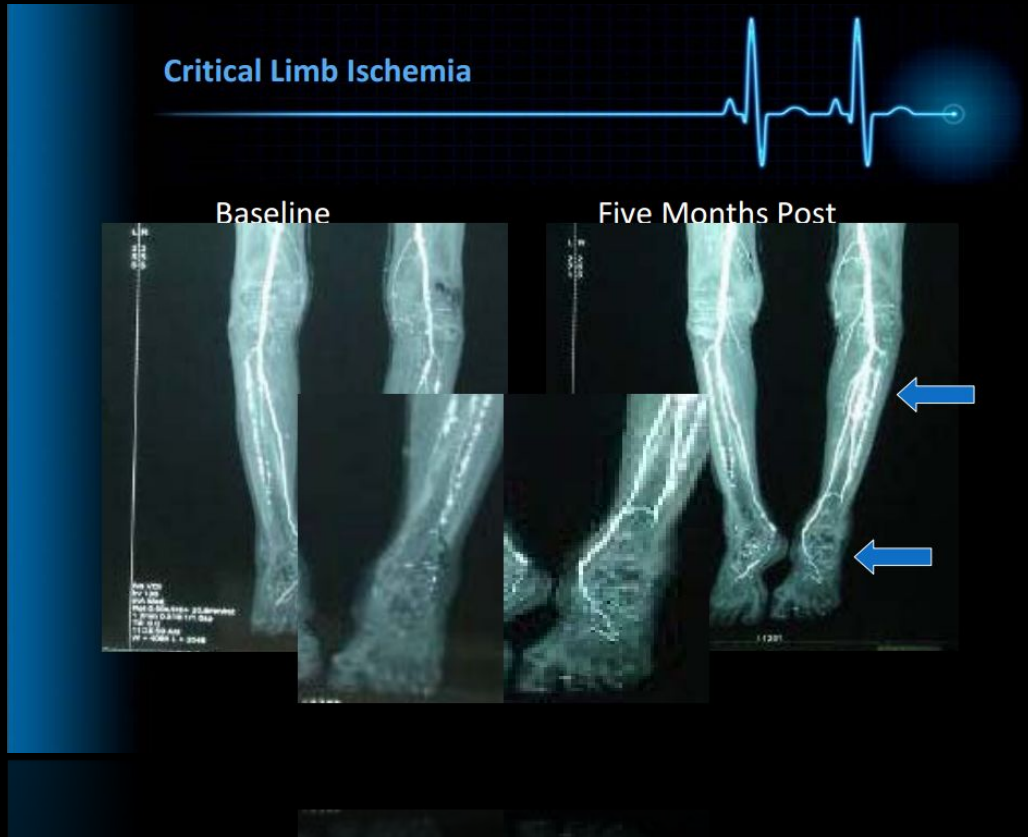
6 Months After Treatment Ejection Fraction 50%

Improvement in Ejection Fraction

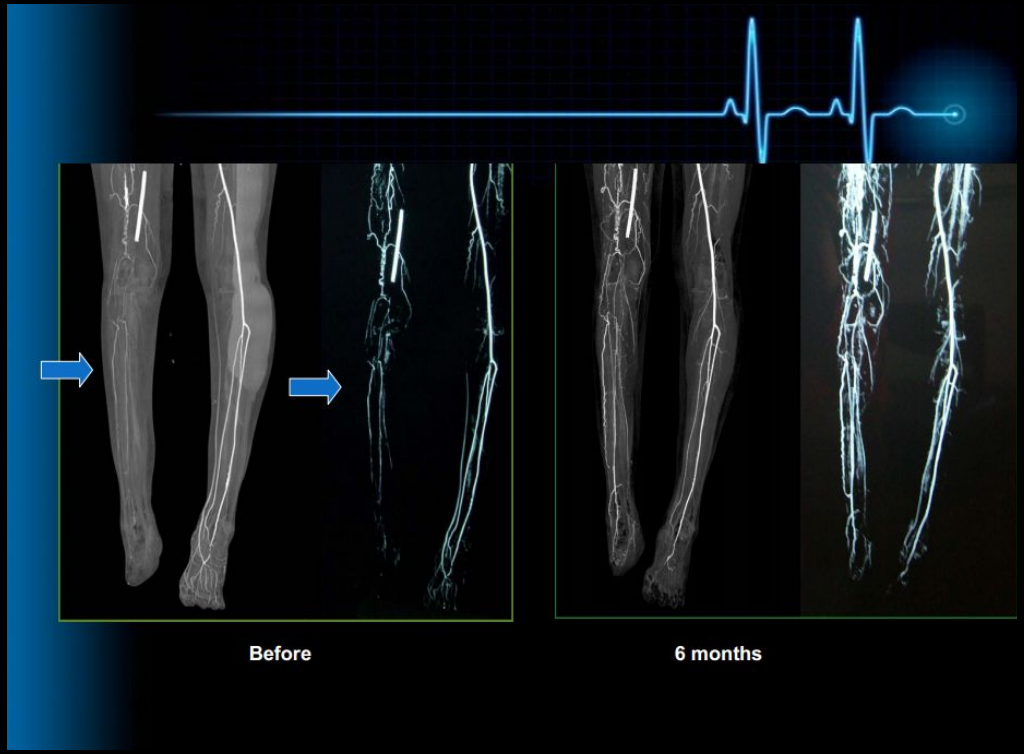
Ischemic Cardiomyopathy



Critical Limb Ischema



Circulatory Improvement



Treatment of Gangrene

Mummification of Extremities

Tissue Regeneration

Regeneration of Tissue

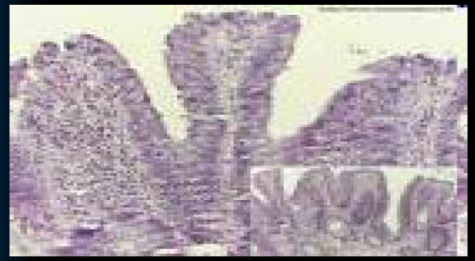
Positive Side Effects

Approximately 60% of treated patients have presented the following

- Improved cognitive function
- Reduction of arthritic symptoms
- Increased energy levels
- Increased physical capacity
- Bald spots growing dark hair
- Visual improvements
- Improved neurological symptoms

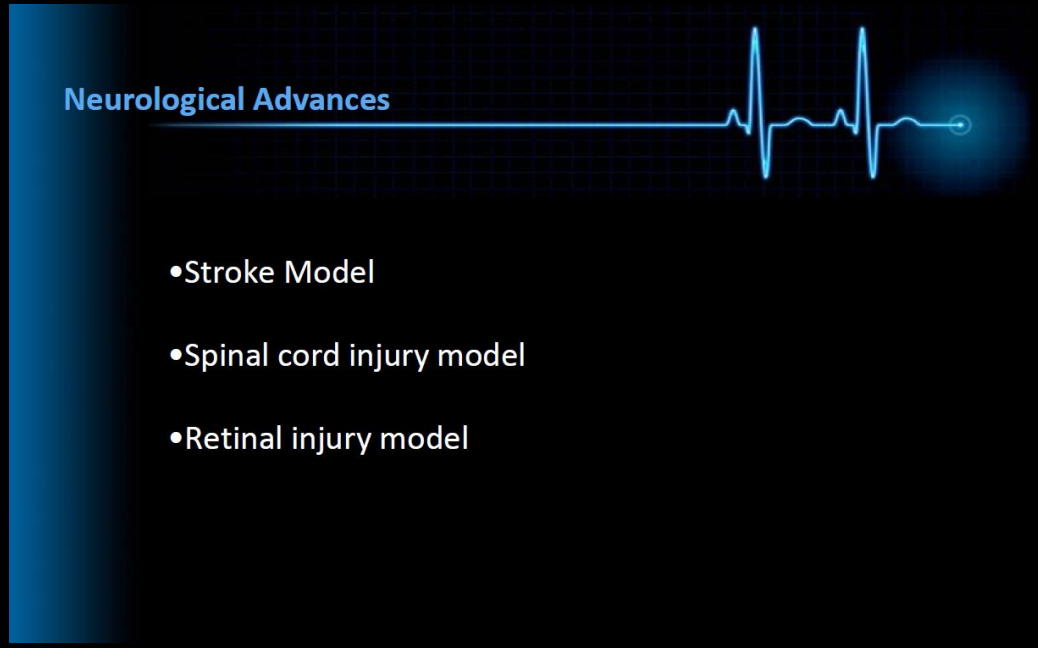
Colon

Colon - Villous Adenoma



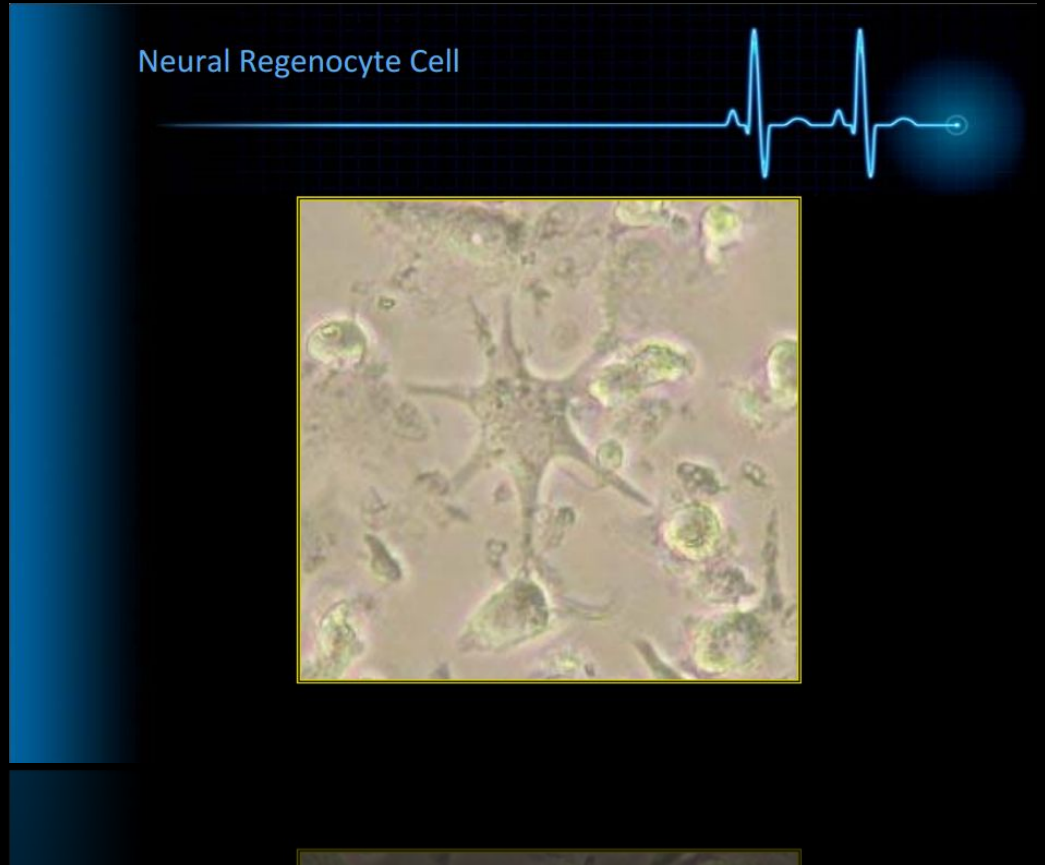
Using Microgravity bioreactors allows for three dimensional architecture and the potential for solid organ generation.

Neurological Advances



- Stroke Model
- Spinal cord injury model
- Retinal injury model

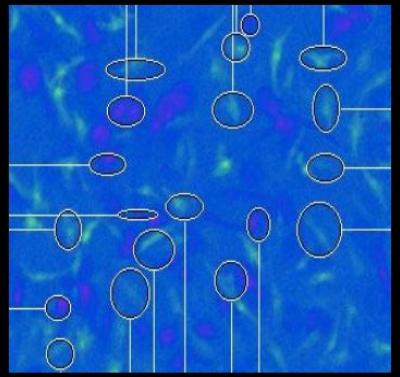
Neural Regenocyte Cell

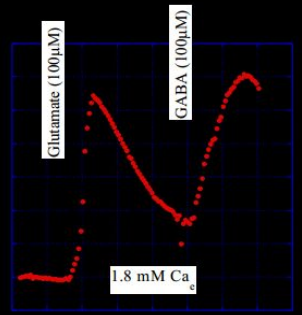


Physiological Activity

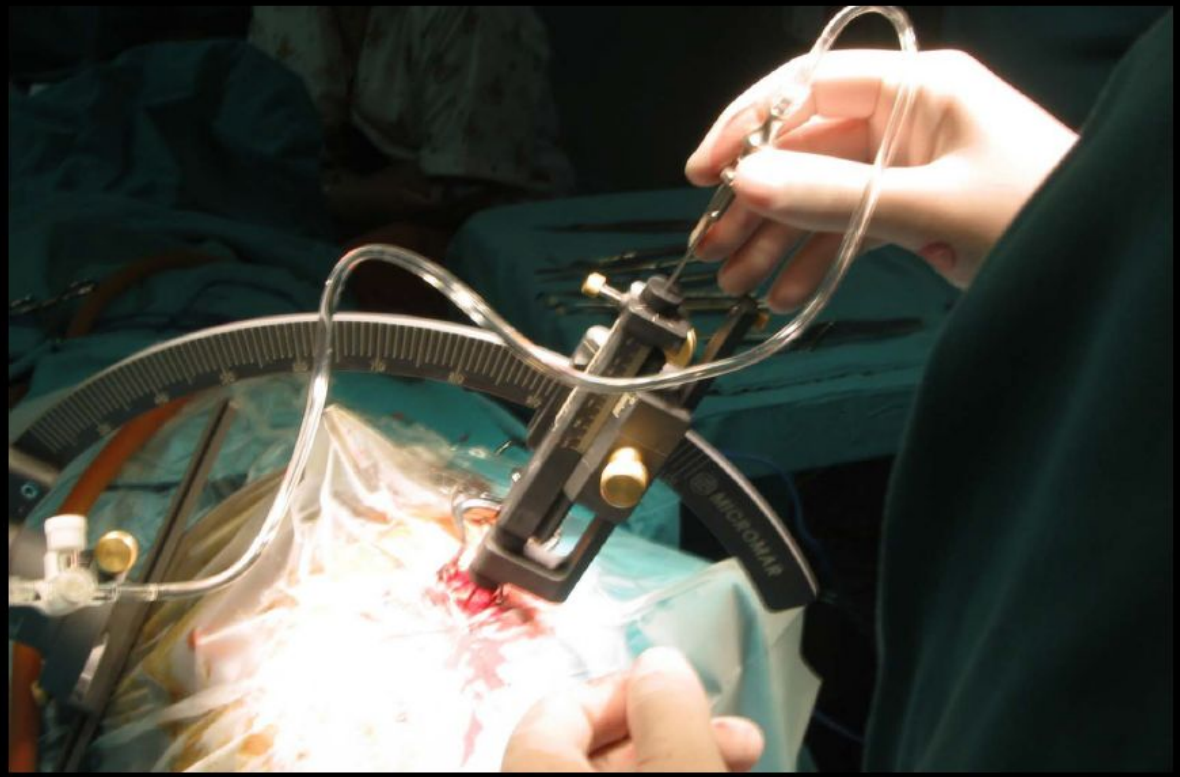
Neural Cell Precursors Physiological Activity

Response to the neurotransmitters Glutamate and GABA.

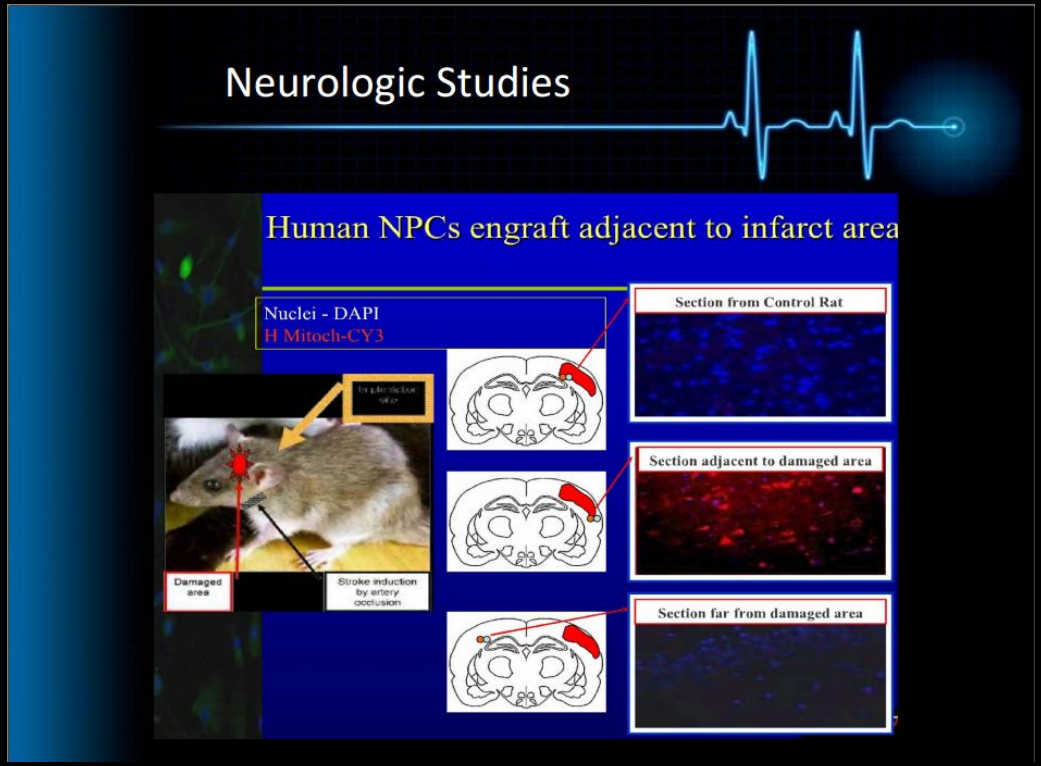




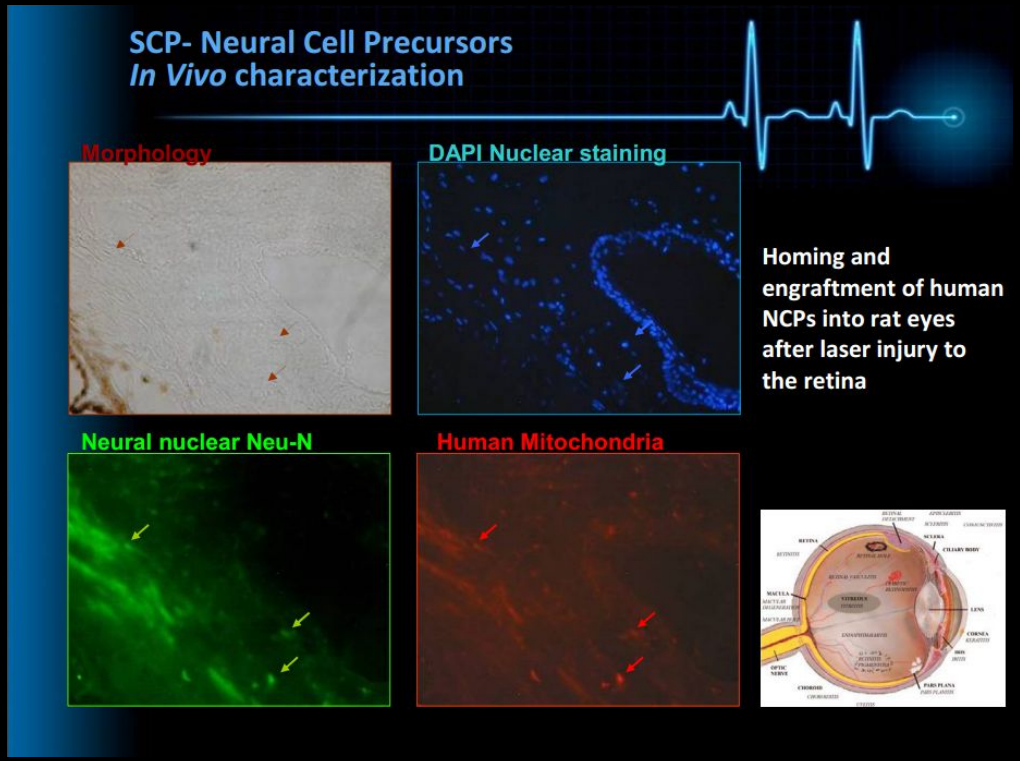
Stereotactic Brain Delivery



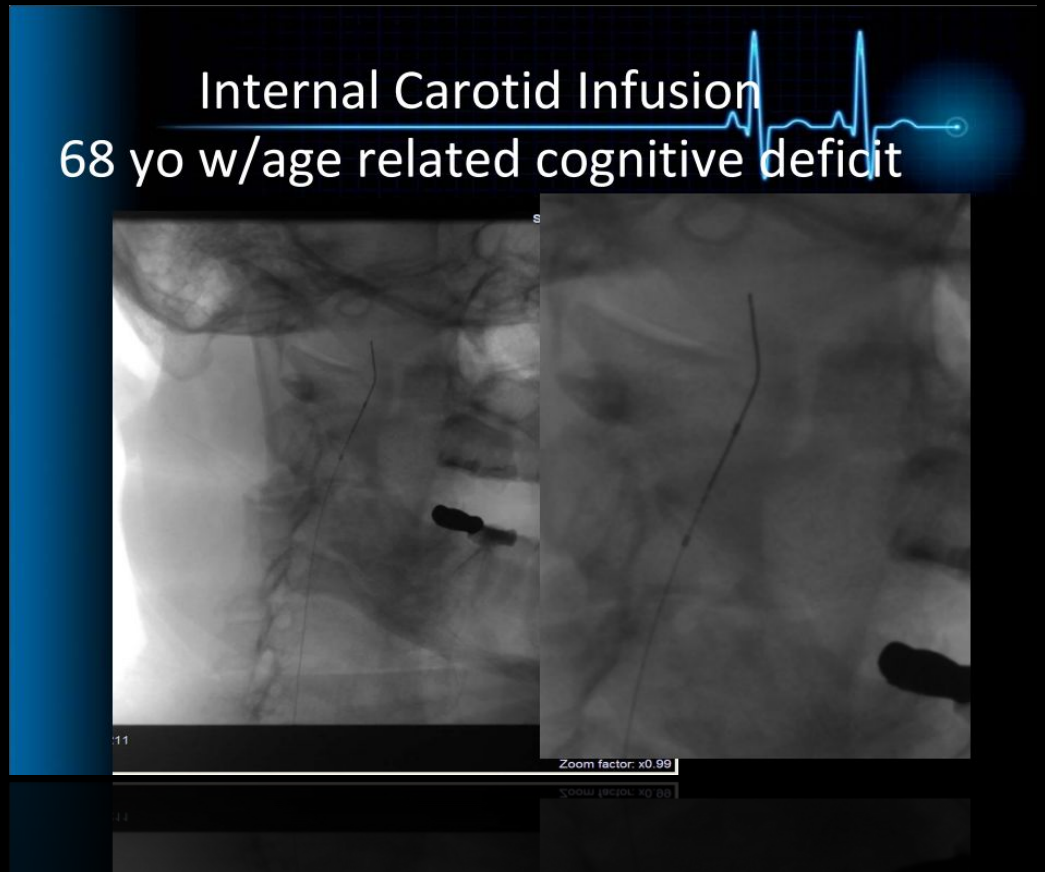
Neurological Studies



Neural Cell Precursors



Carotid Infusion



MUGA Scan

MUGA SCAN

68 yo male with ischemic cardiomyopathy

EXAM#	TYPE/EXAM	RESULT
001406759	NM/CARDIAC MUGA	

PROCEDURE: NUCLEAR MEDICINE MUGA SCAN

INDICATION Cardiomyopathy, stem cell recipient

COMPARISON: Compare with previous examination of July 7, 2008

TECHNIQUE
24.5 mCi of technetium tagged red blood cells was administered for the study.

FINDINGS
The left ventricular ejection fraction is markedly improved at 31%
No regional wall motion abnormality is evident

CONCLUSION
The left ventricular ejection fraction has improved from 15% on July 7, 2008, to 31% on the current study.

Results

Final Analysis

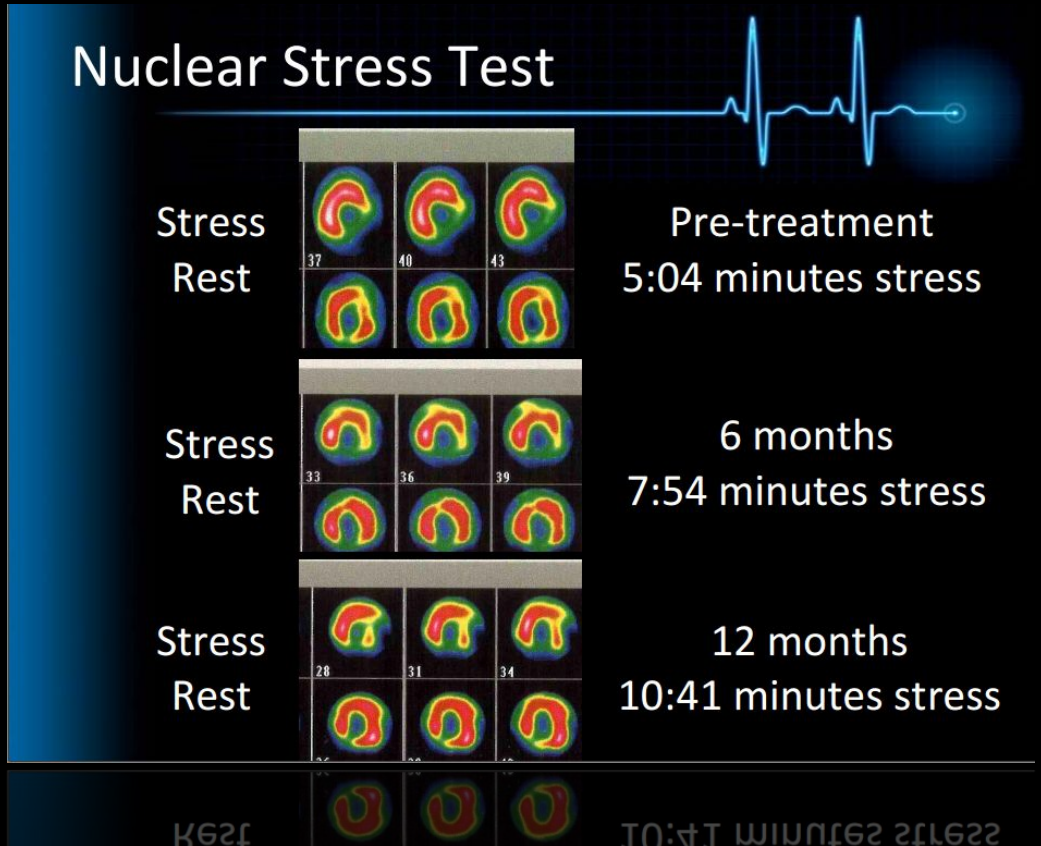
57 yo male w/multi-vessel Coronary Disease
Recommendation: 4 vessel CABG
Treated with Stem Cells

Test	Specification	Results	Pass/Fail
Sterility	No growth	No growth	Pass
Endotoxins	≤ 23.3 EU/ml	< 0.24 EU/ml	Pass
Gram stain	No evidence of bacterial cells	No evidence of bacterial cells	Pass
Viability	≥ 75 %	99.59 %	Pass
Total number of cells	≤ 200×10^6 viable cells	65.54×10^6 viable cells	Pass
Cytometry Analysis	Total % of CD34 stained cells ≥ 1.5%	69 70 %	Pass
	Total number of CD34 stained cells $\geq 1.0\times10^6$	45.68×10^6	Pass
	Number of specific stained cells CD31 bright x AcLDL ($\times10^6$) > 3×10^6 Cells	35.06×10^6 cells	Pass
IL-8 by ELISA	≥ 18.0 ng/ dose	134 9 ng/ dose	Pass

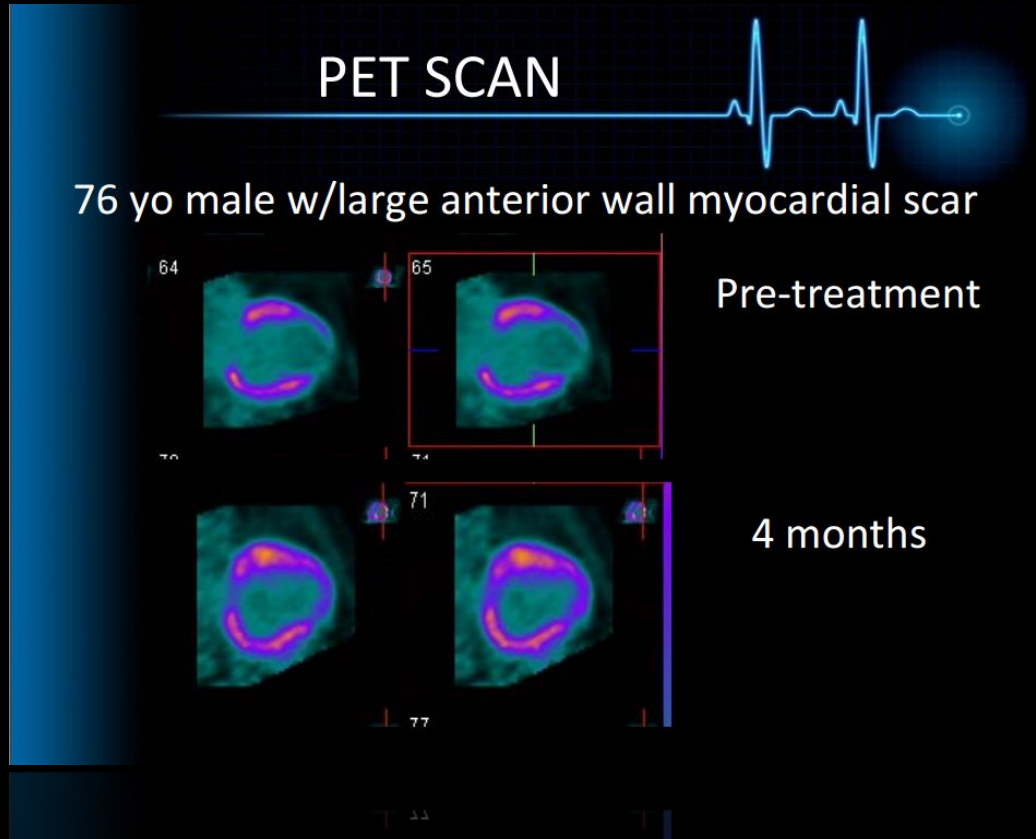
The results Comply with the Release Specifications

Approved	Name	Signature	Date (Israel)	Time (Israel)
Quality Assurance Manager	Kobi Elkayam		8-Apr-08	10:56

Nuclear Stress Test

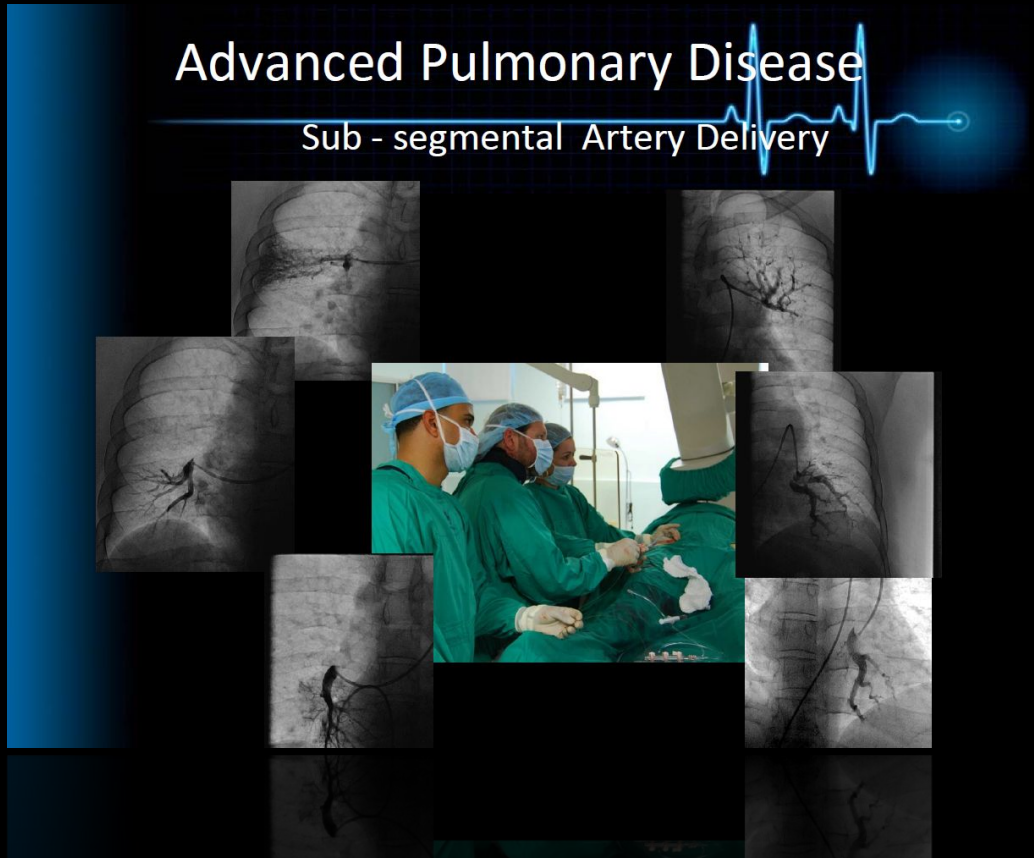


PET Scan


PET SCAN
76 yo male w/large anterior wall myocardial scar
64
65
Pre-treatment
71
4 months

Medical Team

Advanced Pulmonary Disease



Advanced Pulmonary Disease